AUG 18 2003

510(k) SUMMARY

K032287

1.0 Submitted By:

Kim Walker
Senior Regulatory Affairs Specialist
Beckman Coulter, Inc.
200 S. Kraemer Blvd. W-104
Brea, CA 92822-8000
Telephone: (714) 961-4912
FAX: (714) 961-4123

2.0 Date Submitted

July 23, 2003

3.0 Device Name(s):

3.1 Proprietary Names
SYNCHRON® Systems Enzyme Validator Set Levels 1 and 2

3.2 Classification Names
Calibrator. [862.1150]

4.0 Legally Marketed Device

The SYNCHRON® Systems Enzyme Validator Set claims substantial equivalence to the SYNCHRON® Systems Validator Set currently in commercial distribution. (FDA 510(k) Number K984014)

5.0 Device Description

The SYNCHRON Systems Enzyme Validator Set is designed for optimal performance on the SYNCHRON CX (CX4/CX4CE/CX4Δ/CX4PRO, CX5/CX5CE/CX5Δ/CX5PRO, CX7/CX7RTS/CX7Δ/CX7PRO, CX9ALX /CX9PRO) and LX (LX20/LXPRO/LXi) Systems. Each kit of SYNCHRON Enzyme Validator consists of 3 X 5 mL each of Levels 1 and 2 of SYNCHRON Enzyme Validator, two (2) calibration diskettes, one (1) instruction insert, and one (1) Assigned Values sheet.

6.0 Intended Use

The SYNCHRON Enzyme Validator Set, in conjunction with specified enzyme assays on Beckman SYNCHRON® Systems, is intended to provide points of reference in the measurement of selected human enzymes. Use of this product will result in assay values which are compatible with those from methods recommended by the International Federation of Clinical Chemistry (IFCC) and the German Society for Clinical Chemistry (Deutsche Gesellschaft fur Klinische Chemie (DGKCh). Lipase values are specific for the LIP chemistry on SYNCHRON Systems.

7.0 Comparison to the Predicate (Description of the Modification to the Legally Marketed Device)

The SYNCHRON Enzyme Validator Set has been value assigned for ALT, AMY, AST, CK, GGT and LD using the new 2002 IFCC reference method. Additionally, Amylase (AMY) has been added to the list of analytes traceable to the IFCC reference method. There has been no change to the calibrator's formula. AMY was present in the predicate calibrator but was never value assigned.

8.0 Summary of Performance Data

Performance data from validation testing supports equivalency.

Section 1: ADMINISTRATIVE INFORMATION

1.0 Submitted By:

Beckman Coulter, Inc.
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2.0 Sponsor Address/FDA Registration Number

Beckman Coulter, Inc.
200 S. Kraemer Blvd. W-104
Brea, CA 92822-8000
Establishment Registration No. 2050012

3.0 Product Name/Classification Name and Number

Proprietary Names

SYNCHRON® Systems Enzyme Validator Set Levels 1 and 2

Classification Names

Calibrator [862.1150]

4.0 Device Classification

FDA has classified clinical chemistry test systems of this type into Class II.

5.0 Section 514 Compliance

This Special 510(k): Device Modification submission is prepared pursuant to the FDA publication: The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications – Issue Date: March 20, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Kim Walker
Senior Regulatory Affairs Specialist
Beckman Coulter, Inc.
200 S. Kraemer Blvd, M/S - W-104
Box 8000
Brea, CA 92822-8000

Re: k032287
Trade/Device Name: SYNCHRON® Systems Enzyme Validator Set
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: July 23, 2003
Received: July 24, 2003

Dear Ms. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K032287

Device Name: **SYNCHRON® Systems Enzyme Validator Set**

Indications for Use:

The SYNCHRON Enzyme Validator Set, in conjunction with specified enzyme assays on Beckman SYNCHRON® Systems, is intended to provide points of reference in the measurement of selected human enzymes. Use of this product will result in assay values which are compatible with those from methods recommended by the International Federation of Clinical Chemistry (IFCC) and the German Society for Clinical Chemistry (Deutsche Gesellschaft fur Klinische Chemie (DGKCh). Lipase values are specific for the LIP chemistry on SYNCHRON Systems.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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